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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,550	01/26/2001	Komei Washino	Q62780	9592

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EXAMINER

WELLS, LAUREN Q

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 10/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/744,550

Applicant(s)

WASHINO ET AL.

Examiner

Lauren Q Wells

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 4 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 August 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-34 is/are pending in the application.
- 4a) Of the above claim(s) 22-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claims 15-34 are pending. The Amendment filed 8/20/02, cancelled claims 1-14 and added claims 15-34.

Election/Restrictions

Newly submitted claims 22-34 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: a composition and its method of use are distinct.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 22-34 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Specification

The Substitute Specification filed 8/20/02, Paper No. 8, is sufficient to overcome the objection to the specification in the previous Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(i) Claims 1-20 are vague and indefinite, as it is not clear what the composition comprises. Is the composition a therapeutic, nutritional, infusion, or diagnostic composition

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containing compounds wherein at least one member comprises $-^{17}\text{OH}$, $-^{14}\text{NH}$, or $-^{33}\text{SH}$ in its chemical structure? Does the composition comprise the compounds mentioned above and an additional therapeutic, nutritional, infusion, or diagnostic agent? Furthermore, how can the compounds be a sugar, amino acid, additive, or solvent, when they appear to be claimed as therapeutic, nutritional, infusion, or diagnostic agents?

Based on a reading of the specification and the previously cancelled claims, the pending claims wherein examined wherein a therapeutic, nutritional, infusion, or diagnostic composition contains compounds wherein at least one member comprises $-^{17}\text{OH}$, $-^{14}\text{NH}$, or $-^{33}\text{SH}$ in its chemical structure.

(ii) Claim 19 is vague and indefinite, as it is confusing. If the aqueous solvent is water, how can it comprise $-^{14}\text{NH}$ or $-^{33}\text{SH}$?

Claim Rejections - 35-USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 14-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Hopkins et al. (Mag. Res. In Med.).

Hopkins et al. teach compositions comprising oxygen-17 compounds as potential NMR T2 contrast agents and the effects of H_2-^{17}O on protein solutions and living tissues. The reference further teaches that it has incorporated oxygen-17 into larger molecular species, such

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as glucose. Thus, Hopkins et al. and the instant invention both teach compositions comprising oxygen-17 containing glucose or oxygen-17 containing water. See pages 399-403.

The Examiner respectfully points out that the effects of 17-oxygen on the proton bonded thereto are an inherent property of compound. A compound and its properties are inseparable. In re Papesch, 315 F.2d 381, 137 USPQ 43.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hopkins as applied to claims 1-20 above, and further in view of Pines et al. (6,426,058).

Hopkins et al. is applied as discussed above. The reference lacks liposomes.

Pines et al. teach the enhancement of NMR and MRI. Liposomes are disclosed as well known constituents of NMR compositions that are useful in targeting. See Col. 11, lines 16-46.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add the liposomes of Pines et al. to the composition of Hopkins et al. because both are directed to compositions for NMR imaging and Pines teaches that adding liposomes to NMR compositions is useful for targeting a composition to a specific tissue area; thus, one of skill in the art would be motivated to add the liposomes of Pine to the compositions of Hopkins et al. because of the expectation of targeting the oxygen-17 compounds to specific tissue areas.

Response to Arguments

Applicant's arguments with respect to claims 15-21 have been considered but are moot in view of the new ground(s) of rejection. However, to the extent that the arguments may be relevant to the present rejections, the Examiner will address them.

Applicant argues, "the present drug composition enables external detection of the effective circulation or distribution of a therapeutic agent used per se". This argument is not persuasive. The Examiner respectfully points out that the instant claims are directed to a composition, thus this argument is not commensurate in scope with the independent claims. Furthermore, the Examiner respectfully points out that Applicant has not provided any data of unexpected results of the instant invention over that of Hopkins et al.

Applicant argues, "Hopkins et al do not mention drugs containing a compound which comprises at least one member selected from. . .in its chemical structure". This argument is not persuasive. The Examiner respectfully points out that the recitation "selected from the group consisting of therapeutic agents, nutritional tonic agents, infusions and diagnostic agents" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). Furthermore, the Examiner respectfully points out that the instant claims recite glucose containing -17O as a compound and Hopkins also teaches glucose containing -17O as a compound.

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Applicant argues, "Hopkins et al refer to certain compounds incorporating 17O into a larger molecular species, in addition to H217O. . .which means that these compounds essentially need metabolizing in a living body so as to produce the detective H217O". This argument is not persuasive. Again, the Examiner respectfully points out that the instant invention and Hopkins both teach compounds of glucose containing -17O. A compound and its properties are inseparable. In re Papesch, 315 F.2d 381, 137 USPQ 43. Furthermore, the Examiner respectfully points out that the instant claims are directed to a composition. Thus, what occurs in vivo is not relevant to the instant claim's, absent unexpected results.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on M-F (7-5:30), with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (703)305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.



lqw
September 26, 2002